

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
30 March 2006 (30.03.2006)

PCT

(10) International Publication Number
WO 2006/034062 A1

(51) International Patent Classification:
A61F 2/00 (2006.01)

(21) International Application Number:
PCT/US2005/033220

(22) International Filing Date:
16 September 2005 (16.09.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/611,038 17 September 2004 (17.09.2004) US

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

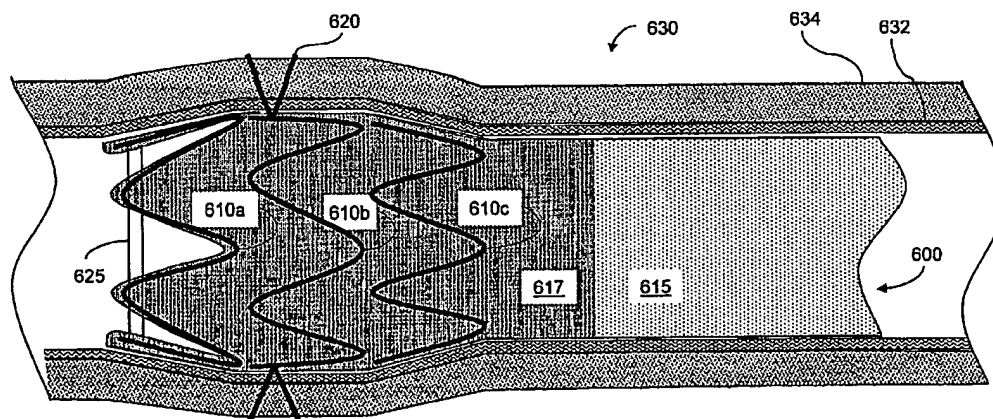
(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: GASTROINTESTINAL ANCHOR



(57) Abstract: The present invention relates to methods and articles for anchoring within a natural bodily lumen. An anchor is adapted to provide differing radially-outward forces along its length, a securing force and a transitional force. Production of these forces can be controlled by varying a physical property of the anchor, such as its stiffness, thickness, or shape. For example, the stiffness of an elongated anchor can be varied from a relatively soft value at its proximal (100a) and distal (100c) ends to a relatively stiff value at its center (100b) by varying the diameter of wire forming the anchor, thereby tailoring it to an intended application. Such force tailoring can be combined with external barbs and used to reliably anchor other instruments, such as feeding tubes and intestinal sleeves.

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GASTROINTESTINAL ANCHOR

RELATED APPLICATION

This application claims the benefit of U.S. Provisional Application No. 60/611,038, filed on September 17, 2004. The entire teachings of the above
5 application are incorporated herein by reference.

BACKGROUND OF THE INVENTION

Anchors are used in the treatment of patients to secure devices at a desired location within a natural bodily lumen. For example, anchors can be used to secure tubes within the digestive tract, such as intestinal sleeves. For example intestinal
10 sleeves anchored within the gastrointestinal tract are described in U.S. Application Nos. 10/339,786 filed on January 9, 2003, claiming priority to U.S. Provisional Application No. 60/430,321 filed on December 2, 2002; 10/858,852 filed on June 16, 2004, claiming priority to U.S. Provisional Application Nos. 60/528,084 filed on December 9, 2003 and 60/544,527 filed on December 14, 2004, incorporated herein
15 by reference in their entirety.

SUMMARY OF THE INVENTION

This invention is generally related to articles and methods for anchoring within a natural bodily lumen, and particularly to articles and methods for anchoring atraumatically.

20 Unfortunately, stiff anchors can traumatize surrounding tissue. This is particularly true in biological applications in which the anchor operates against softer bodily tissues. A stiff anchor may be used within a bodily lumen, such as the intestine to prevent a medical device (*e.g.*, a sleeve) from migrating therein. In some applications, the anchor includes barbs adapted to pierce a portion of the lumen. For
25 the barbs to be effective, at least some of them must engage the tissue at all times. To accomplish this continued engagement, anchors provide a sufficient securing force adapted to maintain the barbs within the tissue. As this securing force can be

substantial, tissue damage at the proximal and distal ends of the anchor are likely to occur.

To anchor within a lumen, anchors generally apply at least some outward force directed toward the inner walls of the lumen. Depending upon the application, the anchoring force can vary from a minimal force (*e.g.*, to hold hooks in position) to a more substantial force (*e.g.*, forming an interference fit). In biological applications the inner walls of a lumen typically contain tissue that is soft and particularly vulnerable to irritation. Thus, in these applications a greater force increases the risk that the anchor will lead to trauma by way of irritation or even tissue damage.

Such irritation and tissue damage are particular concerns for anchors adapted for use within the intestine. Unfortunately, the high mobility of the intestine and the nature of the forces acting on material within the intestine (*i.e.*, peristalsis) complicate anchoring there. Thus, a more substantial force is typically required to secure an intestinal anchor in place.

The present invention relates to an intraluminal anchor adapted for implanting within a natural bodily lumen. The intraluminal anchor includes an elongated anchor having a longitudinal axis adapted for alignment with the natural bodily lumen. The elongated anchor includes a primary anchoring region adapted to expand against the lumen. The anchor also includes secondary anchoring regions disposed along either side of the primary anchoring region. The secondary anchoring regions are also adapted to expand against the lumen with the primary anchoring region expanding to a greater extent than the outer ends of the secondary anchoring regions.

The intraluminal anchor also includes an elongated anchoring member that, when implanted, provides at least two different radial forces at respective positions along its length. These different radial forces act differently upon respective portions of the natural bodily lumen when the device is implanted therein. Namely, at least one of the radial forces is primarily a securing force adapted to anchor within the natural bodily lumen. The other radial force is a transitional force adapted to mitigate damage to the natural bodily lumen. Further, when implanted, the

intraluminal anchor defines an interior lumen allowing for continued functioning of the natural bodily lumen.

The elongated anchoring member can include plural anchoring elements each providing a respective radial force, at least one of the elements providing a different radial force from the others. By positioning each of the plural anchoring elements at a respective position along the length of the intraluminal anchor, the respective radial forces, including the different radial force, are disposed at different lengths along the natural bodily lumen.

The different radial force can be provided by forming one or more of the anchoring elements from a different material than the other anchoring elements. Preferably, the different materials provide different compliance values that produce different radial forces when implanted. Alternatively, or in addition, the different anchoring elements can be formed from the same material but in a different configuration, such as its shape or thickness.

At least some of the anchoring elements can be coupled to each other. For example, in some embodiments at least one joining member is coupled between adjacent anchoring elements, the joining member coupling two or more anchoring elements together.

In some embodiments having plural anchoring elements, at least one of the anchoring elements can be formed from an elongated wire. The elongated wire can be formed in any suitable shape, such as a helix or an oscillating (*i.e.*, wave-shaped) pattern. The wave-shaped pattern distributes the respective radial force over the length of the anchoring element while also improving performance of the anchoring element's respective radial expansion and contraction.

To further enhance its anchoring performance, the intraluminal anchor can include at least one external barb adapted to penetrate tissue of the natural bodily lumen. The external barb is located at a predetermined position along the length of the intraluminal anchor, the corresponding radial force acting to press the barb into the tissue. For example, in a multi-anchoring element embodiment, the at least one external barb can be coupled to one of the anchoring elements. The force of the coupled anchoring element then acts to hold the barb within the tissue.

In some embodiments, the external barb can be a bi-directional barb. Bi-directional barbs are particularly well suited for applications in which the intraluminal anchor is subjected to external forces acting in either direction along the natural bodily lumen. Generally, the bi-directional barb includes a first barb
5 segment adapted to oppose proximal movement and a second barb segment adapted to oppose distal movement. Such barbs are well suited to gastrointestinal applications in which the device is subjected to the substantial axial forces of peristalsis.

Preferably, the anchor is radially collapsible for endoscopic insertion. The
10 intraluminal anchor can also include a drawstring to facilitate repositioning and/or removal. The drawstring, for example, can be provided at a proximal end of the device and be adapted for engagement by a removal device, such as a hook. The drawstring, when engaged, can be pushed or pulled by the removal device, in opposition to the stationary intraluminal anchor, to at least partially collapse at least
15 part of the intraluminal anchor. With a reduced diameter, the device can be removed through, or repositioned within, the natural bodily lumen. In some embodiments, at least a portion of the device is drawn into a retrieval hood, sheath, or overtube prior to removal.

In some embodiments, the intraluminal anchor is coupled to an elongated
20 tube at a proximal end of the tube, the tube being adapted to extend distally within the natural bodily lumen. The elongated anchoring element can be coupled to the elongated tube in any of a number of different ways. For example, the anchoring element can be mechanically fastened using sutures, staples, or the like. Alternatively or in addition, the anchoring element can be bonded to the tube, using
25 a chemical adhesive and/or heat welding. In some embodiments the tube is thin-walled, and flexible. For example, the tube can be formed as a sleeve having extremely thin and floppy walls, the sleeve tending to collapse upon itself. The anchoring element can be secured between at least two overlapping layers of the sleeve. The overlapping layers can then be attached to each other using any available
30 fastening technique including bonding together at least a portion of the overlapping layers of the sleeve.

In other embodiments, the elongated anchoring element can be formed from a homogeneous hollow tube. The thickness of the tube can be altered (*i.e.*, tapered) along the length of the tube, such that different portions of the tube provide different spring forces. When implanted within a naturally bodily lumen, the tapered tube provides different forces along its length and therefore different forces along the bodily lumen according to the thickness of the tube. In some embodiments, the tapered tube can be further modified using known techniques (*e.g.*, laser cutting) to promote radial expansion and contraction of the device.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other objects, features and advantages of the invention will be apparent from the following more particular description of preferred embodiments of the invention, as illustrated in the accompanying drawings in which like reference characters refer to the same parts throughout the different views. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the invention.

Fig. 1A is a schematic diagram illustrating a prior art intraluminal anchor implanted within a natural bodily lumen.

Fig. 1B is a schematic diagram illustrating an embodiment of an intraluminal anchor according to the principles of the invention implanted within a natural bodily lumen.

Fig. 2 is a schematic diagram illustrating an embodiment of an intraluminal anchor.

Fig. 3 is a schematic diagram illustrating an embodiment of a bendable, intraluminal anchor.

Fig. 4A is a schematic diagram illustrating an alternative embodiment of the intraluminal anchor shown in Fig. 1.

Fig. 4B is an exemplary radial-force profile for the intraluminal anchor of Fig. 4A.

Figs. 5A and 5B are schematic diagrams illustrating alternative embodiments of the intraluminal anchor shown in Fig. 2 having cross-linking members.

Fig. 6 is a schematic diagram illustrating an alternative embodiment of the intraluminal anchor shown in Fig. 4A having multiple coupled wave elements.

Fig. 7 is a schematic diagram illustrating a cross-sectional view of an embodiment of the intraluminal anchor device shown in Fig. 2 attached to a tube and implanted within a natural bodily lumen.

Fig. 8 is a schematic diagram illustrating a cross-sectional view of the intraluminal anchor device shown in Fig. 7 implanted within the proximal duodenum.

Fig. 9A is a schematic diagram illustrating an embodiment of a shaped tube.

Fig. 9B is a schematic diagram illustrating an embodiment of an intraluminal anchor formed from the shaped tube shown in Fig. 9A.

Fig. 9C is an exemplary radial-force profile for the intraluminal anchor of Fig. 9B.

DETAILED DESCRIPTION OF THE INVENTION

A description of preferred embodiments of the invention follows.

An anchor is adapted for anchoring within a natural bodily lumen while allowing continued functionality of the lumen and providing minimal trauma to the surrounding anatomy. Such an anchor provides a securing force acting upon the surrounding anatomy to hold the anchor fast, even in the presence of anticipated biological forces. For example, the securing force would hold a gastrointestinal anchor in position even in the presence of peristalsis. Anchoring against such forces, however, may require substantial securing force that could otherwise damage the surrounding tissue.

A cross-section of a natural bodily lumen 20 including an anchor 10b' is illustrated in Fig. 1A. Generally, the lumen defines a natural diameter, D_1 , that may vary over time. The anchor provides a radially-outward securing force directed against the luminal walls. Depending upon the structure of the anchor 10b' and the compliance of the luminal walls, the anchor 10b' when implanted can increase the intraluminal diameter (i.e., D_2) as shown. The sharp transition from the anchored region to the unsupported adjacent region applies a strain to the tissue, particularly at the ends of the anchor 25. As shown, tissue stretching can occur over a first distance Δ_1 . Such a strain can lead to irritation of the tissue or even damage over time.

To offset the possibility of damage due to the securing force, the anchor also provides a transitional force that is different from the securing force and acts upon

an adjacent region of the surrounding anatomy. As shown in Fig. 1B, an anchor 10b" providing a securing force is surrounded on either side by another anchoring element 10a", 10c" providing a lesser, transitional force. The transitional force allows for a more gradual decrease in anchoring force from a central region along the length of the anchor and thus less trauma. Thus, the transition from an expanded diameter D_2 to the natural luminal diameter D_1 occurs over a second distance Δ_2 , that is greater than first distance Δ_1 . By transitioning from unsupported tissue to anchored tissue using a softer anchoring element, the strain to the tissue is reduced, thereby reducing the likelihood of tissue irritation and damage.

By applying different forces at different lengths along the natural bodily lumen, the securing force can be applied, or focused where needed, while the transitional force can distribute the pressure loading to the surrounding anatomy. In particular, the transitional force is a lesser force than the securing force, providing a gradual transition from the luminal region subjected to the securing force, to adjacent, unsupported luminal regions. Preferably, the anchor can be used in combination with another instrument, such as a feeding tube or a gastrointestinal sleeve, to secure the instrument at a predetermined location within the bodily lumen.

Figure 2 schematically illustrates an exemplary embodiment of an intraluminal anchor 100. The anchor 100 has an overall axial-length 'L' measured length-wise with respect to the lumen and defines an interior channel 115 configured to allow continued operation of the lumen when implanted therein. For example, the anchor 100 can have a generally cylindrical shape, having a length 'L', a diameter 'D', and defining an interior channel 115. When implanted, the anchor provides a radially-outward spring force directed against the adjacent walls of the natural bodily lumen (*i.e.*, the anchor includes an annular, radial spring providing a force corresponding to a displacement of the spring along its radius). The radial force includes a securing force, sufficient to secure the anchor 100 in place under anticipated bodily forces. In particular, the outward radial force is varied along the length of the anchor to provide a transitional force, reducing the likelihood of damage to surrounding tissue. When implanted within a natural bodily lumen, the anchor provides a transition along the lumen from soft tissue, to a low compliance

region (*i.e.*, transitional force), to a higher compliance region (*i.e.*, securing force), again to a low compliance region, and ultimately back to unsupported, soft tissue.

Generally, the anchor includes a spring providing the desired securing force. The force produced by the spring is defined by an associated spring rate relating to its compliance or stiffness. The spring rate can be determined by one or more anchor features including its type of material, material thickness, dimensions, and shape. As a radial spring, a greater force results from a greater radial displacement. For intraluminal applications, such a radial spring preferably has a relaxed diameter (*i.e.*, no load diameter) that is greater than the largest anticipated intraluminal diameter. Thus, the implanted anchor is always subjected to a compressive force causing radial compression and leading to an opposing securing force. Compliant anchors are described in U.S. Application No. 11/147,992 filed on June 8, 2005, incorporated herein by reference in its entirety.

In many applications the anchor remains sufficiently compliant, when implanted, to conform to the walls of the lumen over a full range of motion. For example, an anchor implanted within the proximal duodenum of an adult human may experience intraluminal diameter variations from about 25-millimeters or less, to greater than 50-millimeters.

As suggested by Fig. 2, the anchor 100 can provide a varied force by using plural anchoring elements. For example, the anchor 100 can include three or more different anchoring elements 110a, 110b and 110c (generally 110), as shown. Each of the anchoring elements 110a, 110b and 110c can be annular, as shown, and occupy a respective axial sub-length ' l_1 ,' ' l_2 ,' and ' l_3 .' Further, each of the anchoring elements 110 can be separated from its neighboring anchoring element by a respective distance ' s_1 ,' ' s_2 .' In some embodiments, the one or more of the distances can be negative, suggesting that the elements overlap. The overall length of the anchor 100 is determined as the sum of the sub-lengths of the anchoring elements and any distances provided therebetween. Each of the annular anchoring elements 110 can be sized and shaped to conform to the walls of the surrounding lumen with its opening collinearly aligned with a luminal axis.

In some embodiments, the anchoring elements 110 are coupled together using a respective cross-linking, or joining member 120a, 120b (generally 120), as

shown. The joining member 120 can be a rigid member or strut, such as a wire or rod. Use of rigid struts can reduce or substantially eliminate axial compression of the device. Alternatively or in addition, the joining member 120 can be flexible, such as a wire, tape, or thread (*e.g.*, a suture). Such flexible members can permit
5 axial compression but not expansion, so the length can be less than or equal to a maximum length. If axial compression and expansion is desired, the joining members 120 can include elastic elements. Such flexibility can be beneficial to both patient comfort and anchoring effectiveness. In some embodiments, the joining members 120 are formed integrally to the anchoring elements 110 themselves.

10 An embodiment of a flexible elongated anchor 200 is illustrated in Fig. 3. The elongated anchor 200 can include more than one anchoring element 210a, 210b, 210c, each capable of independent movement with respect to the other elements. The anchor 200 may include joining members 220a, 220b, but they are selected and positioned to allow a desired flexibility. For example, rigid joining members can be
15 aligned along one side of the anchor 200, allowing the anchor to bend towards that side.

An alternative embodiment of an intraluminal anchor 300 is illustrated in Fig. 4A. The anchor 300 includes multiple anchoring elements 310a, 310b, 310c in a collinear arrangement with adjacent elements 310 abutting. A corresponding
20 force-versus-distance graph for the anchor 300 is illustrated in Fig. 4B. In particular, the graph illustrates the different radially-outward forces provided by each of the anchoring elements 310 (Fig. 4A) versus its respective distance as measured along a central axis of the anchor 300. As shown for the exemplary embodiment of Fig. 4A, the greater radial force is provided by the central element
25 310b, having a representative force of F_2 . The corresponding force can be substantially constant across the axial length subtended by the second anchoring element 310b (*i.e.*, from $L/3$ to $2L/3$, assuming all three elements are of equal length $L/3$). Similarly, forces F_1 and F_3 provided by the adjacent first and third anchoring elements 310a, 310c are lesser forces, as shown in the graph (*e.g.*, at region 320).
30 The greater force F_2 corresponds to a securing force to hold the anchor in place when implanted; whereas, the lesser forces F_1 and F_3 correspond to transitional forces lessening the likelihood of damage to surrounding tissue.

In some embodiments, however, the structure of the anchoring elements 310 allows the elements to provide different forces along their respective sub-lengths. As the anchoring elements 310 are radial springs, they have an associated spring constant. The radial force provided by the anchoring element 310 is thus a result of
5 the spring constant and the amount of radial compression. Anchoring element configurations that allow for varied compression along the anchor sub-length will lead to a corresponding varied radial force. For example, if the outer anchoring elements 310a, 310c are each coupled at one end to the central anchoring element 310b, they may have a different diameter on each end. As the central anchoring
10 element 310b is stiffer, it may have a greater diameter than a less stiff element. In general, there is no limit to the number of anchoring elements that can be provided or to the particular stiffness profile desired.

The securing force produced by the anchor can include a radial component directed outward and pressing against the walls of the surrounding lumen. The
15 securing force can also include an axial component provided by a barb. The magnitude of the securing force preferably depends on the intended application being selected to sufficiently secure the anchor without being excessive. Limiting the maximum force is important as substantial forces acting against the luminal walls are more apt to traumatize the surrounding tissue.

20 In some embodiments, the radially-outward force of an anchor is varied by varying the stiffness (or compliance) of the anchor along its length. Such a feature provides for greater flexibility in tailoring the anchor to its intended delivery location. For example, the thickness of the anchor member can be varied to control the desired stiffness, such that a portion of the anchor is relatively stiff, whereas
25 another portion of the anchor is relatively soft. In this manner, the stiffer portion of the anchor can be used to distend that portion of the bodily lumen within which it is implanted. To reduce irritation, the stiffness is then reduced towards the proximal and distal ends of the anchor to reduce any trauma to the tissue of the bodily lumen.

For example, a side view of a flexible intraluminal anchor 400' is illustrated
30 in Fig. 5A. By using different anchoring elements 410a', 410b', 410c', interconnected by joining members 420a', 420b' (generally 420') as shown, the anchor 400' is allowed to flex and bend. The joining members 420' are not

necessary for embodiments in which the elements 410 are each coupled to the same tube or sleeve. The anchoring elements 410' are each formed from a respective continuous wire fashioned into the oscillating, wave-shaped pattern shown. Viewed along an axis (not shown), the anchor 400' would appear as an open circle or hoop.

5 Wave-shaped anchors and related matters are described in U.S. Application No. 10/858,852 filed on June 1, 2004 and claiming priority to U.S. Provisional Application Nos. 60/528,084 filed on December 9, 2003 and 60/544,527 filed on December 13, 2004. The entire teachings of these applications are incorporated herein by reference in their entirety.

10 In one embodiment, the central anchoring element 410b' is formed from a relatively thick wire, such as a 0.023 inch diameter Nitinol wire. The additional anchoring elements 410a', 410c' are formed from a thinner wire, such as a 0.014 inch diameter Nitinol wire. Using wires formed from the same material, the thicker wire results in a greater stiffness than the thinner wire. Thus, the central anchoring
15 410b' element provides a greater radially-outward force when compressed than either of the two surrounding anchoring elements 410a', 410c'. The spring rate can also be varied by altering the axial length of a wave-shaped anchoring element, shorter elements being stiffer than longer ones. Also, the spring rate can be varied by altering the number of oscillations for a give anchoring element, elements with more
20 oscillations being stiffer.

The wires can be formed from any suitable material, such as metals, metal alloys (*e.g.*, stainless steel and Nitinol), and/or synthetic materials (*e.g.*, plastic). Preferably, the material is bio-compatible, although it is possible to use non bio-compatible material that is coated or encapsulated in a bio-compatible material.
25 Anchoring can be accomplished using an interference fit between the intraluminal anchor and the inner walls of the lumen. Alternatively or in addition, anchoring can be accomplished using other means including sutures, staples, surgical adhesives and/or barbs or hooks. In the exemplary embodiment, at least one external barb 425' is be attached to the central anchoring element 410b'. When implanted, the barb
30 425' is held in place within muscular tissue by the stiffness and corresponding radially-outward force of the 0.023 inch diameter wire. The central anchor element 410b provides a substantial force to keep the barb 425' inserted into the surrounding

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tissue. Without the first and third anchoring elements 410a', 410c', the securing force provided by the middle anchoring element 410b' could lead to tissue irritation or even damage at the ends of the element 410b'.

The anchoring elements described above can be formed into any number of different shapes. In some embodiments, each of the anchoring elements is formed in a wave shape. Thus, a linear element (*i.e.*, a wire) is contoured into an oscillating manner along a cylindrical surface at a distance (*i.e.*, a radius) from a central axis. Such a wire form can be shaped on a cylindrical mandrel. The two ends of the wire are joined together (*e.g.*, crimped, soldered, or chemically or thermally bonded) forming a continuous structure. An anchoring element thus formed provides a relatively small surface area in contact with the natural bodily lumen, while allowing the anchor to provide a relatively large diameter (*e.g.*, 25 to 50 or more millimeters for gastrointestinal applications). The oscillations result in relatively straight segments 412a, 412b (generally 412) interconnected at nodes 414a, 414b (generally 414). When compressed in a radial direction, the nodes 414 flex allowing the relatively straight segments 412 to become more aligned with respect to each other. Thus, the diameter of the anchor 400' can be reduced substantially to allow for its insertion and/or removal through a relatively small diameter. For example, in some intestinal applications, a 50-millimeter diameter device is adapted to be inserted through a 12-millimeter diameter catheter. When released, the anchor 400' expands with spring force against the walls of the bodily lumen.

The anchoring elements 410a', 410b', 410c' may be separated by respective distances s_1 , s_2 as shown, or one or more of the elements may be adjacent or even overlapping. An alternative embodiment of a wave-shaped wire anchor 400'' is illustrated in Fig. 5B. The anchoring 400'' also includes multiple anchoring elements 410a'', 410b'', 410c'' that may or may not be interconnected by joining members 420a'', 420b''. As shown, one or more of the anchoring elements 410a'', 410b'', 410c'' can overlap another anchor element to varying degrees. At least one advantage of such an overlap is a reduction in the overall length of the anchor 400''. Such an overlap can also be used to achieve a desired force-versus-distance profile of the anchor 400'', leading to a more gradual transition of the forces distributed along the axis.

A side view of an alternative embodiment of an intraluminal anchor 500 is illustrated in Fig. 6. The anchor 500 includes multiple anchoring elements 510a, 510b, 510c, again shown as wave-shaped elements for illustrative purposes, that are interconnected to each other. The anchoring elements 510a, 510b, 510c can be
5 interconnected by mechanical fasteners, chemical adhesives, thermal bonding, welding, soldering, and/or weaving. The interconnection may be fixed, or in the case of a weave, capable of longitudinal compression.

As described above, the intraluminal anchor can be used to anchor an elongated tube within a natural bodily lumen. An exemplary device 600 including
10 an intraluminal anchor, similar to the one described above in reference to Fig. 5A, and coupled to the proximal end of an elongated tube 615 is illustrated in Fig. 7. The tube 615 may be rigid, semi-rigid or flexible. Gastrointestinal sleeves and related matters are described in U.S. Application No. 10/339,786, filed January 9, 2003, which claims the benefit of U.S. Provisional Application No. 60/430,321,
15 filed December 2, 2002; and U.S. Application No. 10/726,011, filed on December 2, 2003, which claims the benefit of U.S. Provisional Application No. 60/512,145 filed October 17, 2003. The entire teachings of all of these applications are incorporated herein by reference.

The anchoring elements 610a, 610b, 610c (generally 610) can be bonded to
20 the tube (e.g., chemically bonded using an adhesive, or thermally bonded). The anchoring elements 610 can also be mechanically coupled to the elongated tube 615. For example, the anchoring elements 610 can be coupled using a suture, a surgical staple, and/or by threading the anchoring element itself through perforations in the elongated tube.

25 In some embodiments, the anchoring elements 610 are encapsulated within the elongated tube 615. For example, the elongated tube 615 can be formed as a sleeve. A portion the sleeve can then be used to encapsulate the anchoring elements by folding one end of the sleeve back upon itself to cover both the interior and exterior of the anchoring elements 610. The portions of the elongated tube forming
30 the overlapping portion 617 can then be coupled together, thereby capturing the anchoring elements 610 and securing them in place with respect to each other and with respect to the elongated tube 615. For example, the overlapping portions of the

tube 617 can be bonded together (e.g., chemically bonded using an adhesive, or thermally bonded). Alternatively or in addition, the overlapping portions of the tube 617 can be mechanically fastened together. For example, the overlapping portions of the elongated tube 617 can be coupled together using sutures, staples, clasps, or
5 any other suitable mechanical fastener.

As shown, the anchor 600 can include barbs 620 that protrude externally from the anchor 600 to penetrate the surrounding tissue. For illustrative purposes, the device 600 as implanted within a portion of an animal's intestine 630 illustrated in cross section. Shown are the intestinal wall 630 including an inner mucosal layer
10 632 in communication with the anchor 600 and a surrounding layer of muscular tissue 634. Preferably, the barbs 620 are adapted to penetrate the mucosal layer 632 and into the muscular tissue 634 of the intestine 630. In some embodiments, the barbs 620 actually penetrate the outer walls of the intestine 630. Thus, the barbs 620 provide an axial securing force component, with the anchoring element 610b
15 providing a securing force adapted to maintain the barbs into engagement with the muscular tissue 634.

To ensure that the barbs 620 remain secured to the muscular tissue during implantation, the anchoring element to which the barbs 620 are coupled should be relatively stiff. Thus, the stiffness of the supporting anchoring element 610b
20 maintains a radial force ensuring that the barbs 620 are driven into the tissue. In some embodiments, the stiffness is sufficient to force the supporting anchoring element 610b through the mucosal layer 632, abutting it to the layer of muscular tissue 634.

In some applications, however, the stiffness of the anchoring element 310b
25 can lead to irritation and possibly damage to the surrounding tissue. To reduce the possibility of such irritation or damage, additional anchoring elements 610a, 610c are provided on either side of the anchoring element 610b. Preferably, the additional anchoring elements 610a, 610c are less stiff (i.e., softer) than the central anchoring element 610b. In this manner, the transition between unanchored portions of the
30 lumen and the stiff anchoring element 610b is spread over a larger surface area to achieve the desired anchoring force at the barbs 620 in a gradual manner. Thus, the

additional anchoring elements 610a, 610c provide a strain relief on both sides of the stiff anchoring element 610b to minimize trauma to the tissue, as shown in Fig. 1B.

An exemplary embodiment of an intraluminal anchor anchoring an elongated flexible sleeve within the intestine of an animal is illustrated in Fig. 8. A lower
5 portion of the stomach 700 is shown terminating in a pyloric sphincter 705. Distal to the sphincter 705 is the proximal duodenum 715, sometimes referred to as the duodenal bulb. The device of Fig. 7 is implanted with the anchor being situated distal to the pyloric sphincter 705, preferably within the duodenal bulb 715. The sleeve 600 can extend through the duodenum 710 and into the jejunum 720.

10 As described above in reference to wire anchoring elements, the radial force, or stiffness can be controlled by varying a physical property of the anchoring element. This approach can also be extended beyond wire examples. For example, the elongated anchoring element can be formed from a tapered tube. To vary the radial force, or stiffness, the tube can be shaped to vary its wall thickness. The axial
15 taper can be accomplished by injection moulding to a desired shape and/or by removing material from a solid elongated tube. The result in either case is an anchoring element having differing thicknesses along its central axis. Figure 9A illustrates a cross-sectional view of an exemplary tube 800 after having both ends tapered from a thicker middle section. Thus, the thinner ends 810 are achieved by
20 removing extra material 820. For example, a stainless steel or alloy (e.g., Nitinol) tube 800 can be shaped by grinding it and/or turning it on a lathe to selectively remove material along its length. As shown, the tube 800 can be tapered from a relatively thick portion along the tube middle, to a relatively thin portion at the tube's ends (with this approach, any conceivable profile is possible).

25 The shaped tube 800, once tapered, can be further processed to form an expandable anchor. For example, referring to Fig. 9B, apertures 920 can be cut into the shaped tube 900 walls using a laser. The remaining portions of the shaped tube 910, once cut, can form a continuous structure such as the interconnected network of struts 910 shown, or even a wave structure as described above. Again, the resulting
30 structure provides an interior lumen 915, while also being radially compressible. A corresponding force-versus-distance profile for the exemplary tube 900 is illustrated in Fig. 9C.

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As will be appreciated by those of skill in the art, there are many potential variations to these methods and articles. Those variations are encompassed by this invention.

5 While this invention has been particularly shown and described with references to preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the scope of the invention encompassed by the appended claims.

CLAIMS

What is claimed is:

1. An intraluminal anchor comprising:
5 an elongated anchor adapted for implanting within a natural bodily lumen, a central axis of the elongated anchor adapted for alignment with the natural bodily lumen, the elongated anchor including:
 a primary anchoring region adapted to expand against the lumen; and
 a secondary anchoring region disposed at either side of the primary
10 anchoring region also adapted to expand against the lumen, the primary anchoring region expanding to a greater extent than the outer ends of the secondary anchoring regions.
2. The intraluminal anchor of claim 1 wherein the elongated anchor comprises a
15 plurality of anchoring elements, at least one of the anchoring elements relating to the primary anchoring region and at least two other of the anchoring elements relating to the secondary anchoring regions.
3. The intraluminal anchor of claim 2, wherein the anchoring element relating
20 to the primary anchoring region and the least two other of the anchoring elements relating to the secondary anchoring regions comprise different materials.
4. The intraluminal anchor of claim 2, wherein the anchoring element relating
25 to the primary anchoring region and the least two other of the anchoring elements relating to the secondary anchoring regions comprise substantially the same material having a different thickness.
5. The intraluminal anchor of claim 2, wherein at least one of the plurality of
30 anchoring elements is formed from an elongated wire.

6. The intraluminal anchor of claim 2, wherein at least one of the plurality of anchoring elements is a wave-shaped element.
- 5 7. The intraluminal anchor of claim 2, wherein at least one of the plurality of anchoring elements comprises at least one external barb adapted to penetrate tissue of the natural bodily lumen, the respective anchoring element expanding against the lumen and adapted to hold the barb within the tissue.
- 10 8. The intraluminal anchor of claim 7, wherein the external barb is a bi-directional barb, comprising a first barb segment adapted to oppose proximal movement and a second barb segment adapted to oppose distal movement.
- 15 9. The intraluminal anchor of claim 2, further comprising at least one joining member coupled between at least two of the plurality of anchoring elements.
10. The intraluminal anchor of claim 2, wherein at least one of the plurality of anchoring elements is coupled to a proximal end of an elongated tube, the tube adapted to extend distally within the natural bodily lumen.
- 20 11. The intraluminal anchor of claim 10, wherein the elongated tube is adapted to be anchored in the proximal duodenum, the tube extending distally within the intestine.
- 25 12. The intraluminal anchor of claim 10, wherein the elongated tube is thin-walled, collapsing upon itself.
- 30 13. The intraluminal anchor of claim 1, further comprising at least one external barb positioned at the primary anchoring region and adapted to penetrate tissue of the natural bodily lumen, the expanding against the lumen adapted to hold the barb within the tissue.

14. The intraluminal anchor of claim 13, wherein the external barb is a bi-directional barb, comprising a first barb segment adapted to oppose proximal movement and a second barb segment adapted to oppose distal movement.
- 5 15. The intraluminal anchor of claim 1, further comprising an elongated tube coupled at its proximal end to the elongated anchor, the tube adapted to extend distally within the natural bodily lumen.
- 10 16. The intraluminal anchor of claim 15, wherein the elongated tube is adapted to be anchored in the proximal duodenum, the tube extending distally within the intestine.
- 15 17. The intraluminal anchor of claim 15, wherein the elongated tube is thin-walled, collapsing upon itself.
18. The intraluminal anchor of claim 15, wherein the elongated anchoring element is coupled to the tube between overlapping layers of the tube.
- 20 19. The intraluminal anchor of claim 1, wherein the anchor is radially collapsible for endoscopic insertion.
- 25 20. The intraluminal anchor of claim 1, wherein the elongated anchor is formed from a homogeneous hollow tube having a tube wall of differing thickness along its length, the tube wall defining apertures adapted to allow radial variation of the tube.
21. The intraluminal anchor of claim 1, wherein the primary and secondary anchoring regions comprise different spring rates.
- 30 22. The intraluminal anchor of claim 1, wherein the primary anchoring region is central.

23. A method for anchoring within a natural bodily lumen comprising:
providing a radially-outward securing force acting upon a first region
of the natural bodily lumen;
providing a radially-outward transitional force acting upon either side
5 of the first region of the natural bodily lumen; and
allowing continued function of the natural bodily lumen, radially-
outward transitional force being adapted to mitigate damage to the natural
bodily lumen.
- 10 24. The method of claim 23, wherein a first anchoring elements providing the
radially-outward securing force and a second anchoring element provides the
radially-outward transitional force.
- 15 25. The method of claim 23, further comprising piercing interior walls of the
natural bodily lumen with at least one external barb, the radially outward
securing force driving the at least one barb into the interior wall.
- 20 26. The method of claim 25, further comprising inhibiting movement in either
direction along the natural bodily lumen using the at least one barb.
27. The method of claim 23, further comprising at least partially radially
collapsing the elongated anchoring element for insertion of the intraluminal
anchor into the natural bodily lumen.
- 25 28. The method of claim 23, further comprising at least partially radially
collapsing at least a portion of the elongated anchoring element for removal
of the intraluminal anchor from the natural bodily lumen.
- 30 29. An intraluminal anchor comprising:
means for providing a radially-outward force upon a first region of
the natural bodily lumen; and
means for providing a different radially-outward force upon a distal
region of the natural bodily lumen, while allowing continued function of the

natural bodily lumen, wherein at least one of the radially-outward forces is a securing force adapted to anchor within the natural bodily lumen and the other radially-outward force is a transition force adapted to mitigate damage to the natural bodily lumen.

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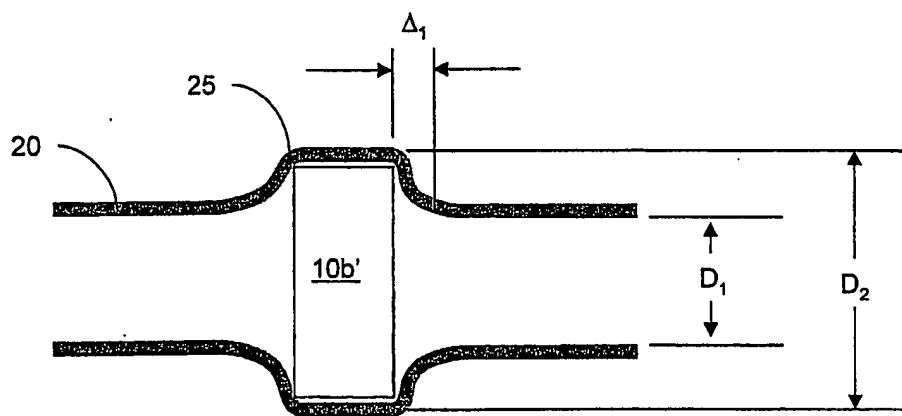


FIGURE 1A

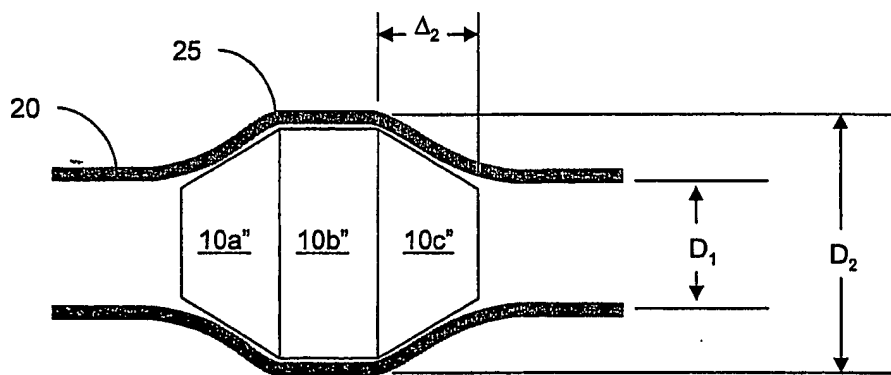


FIGURE 1B

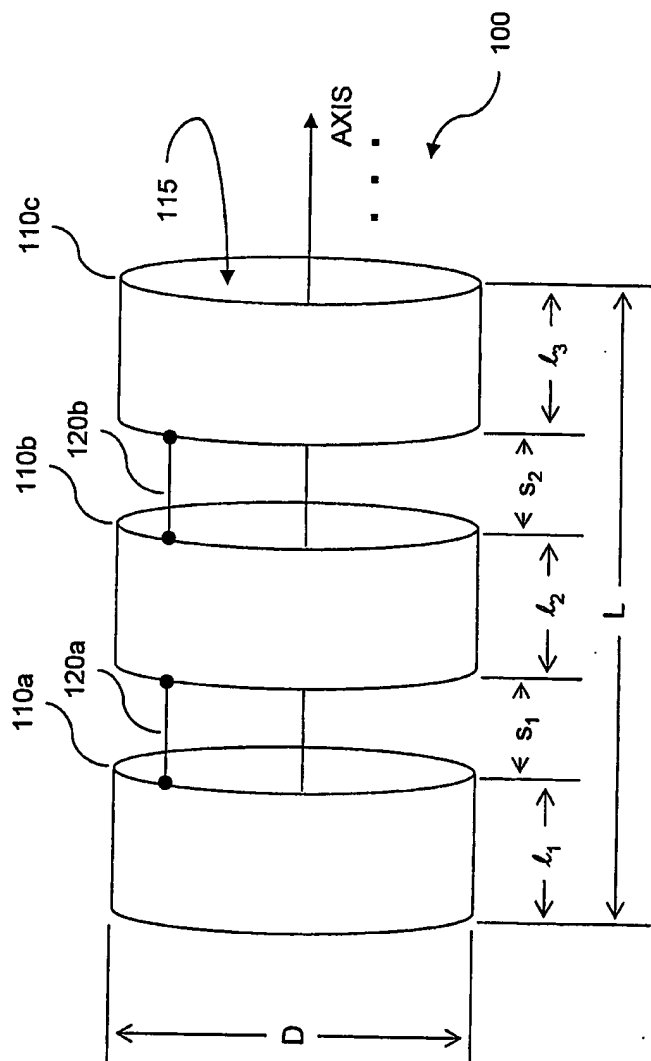


FIGURE 2

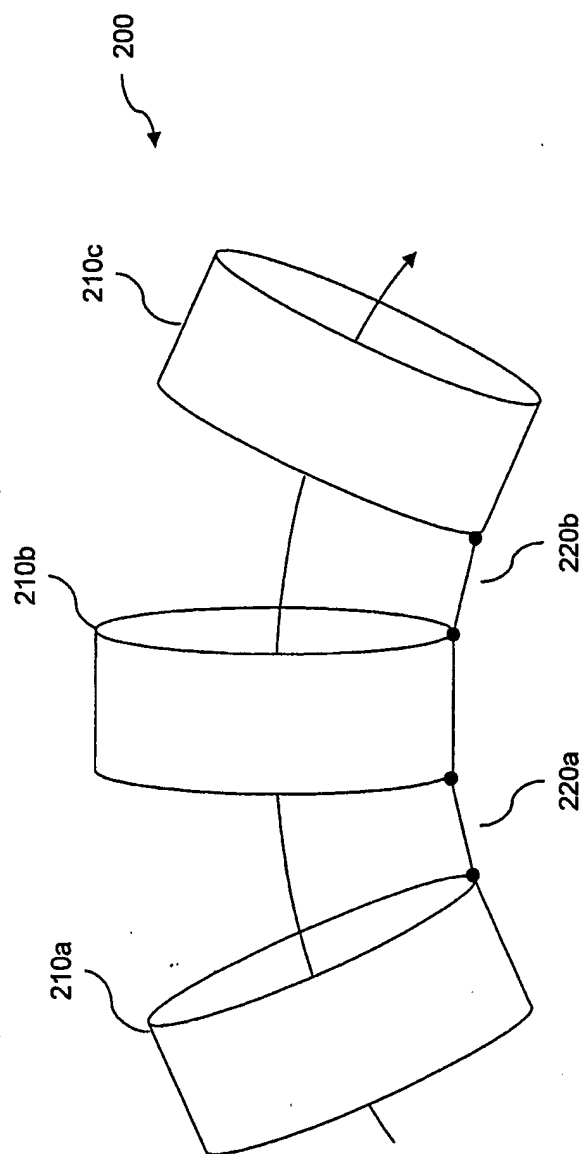


FIGURE 3

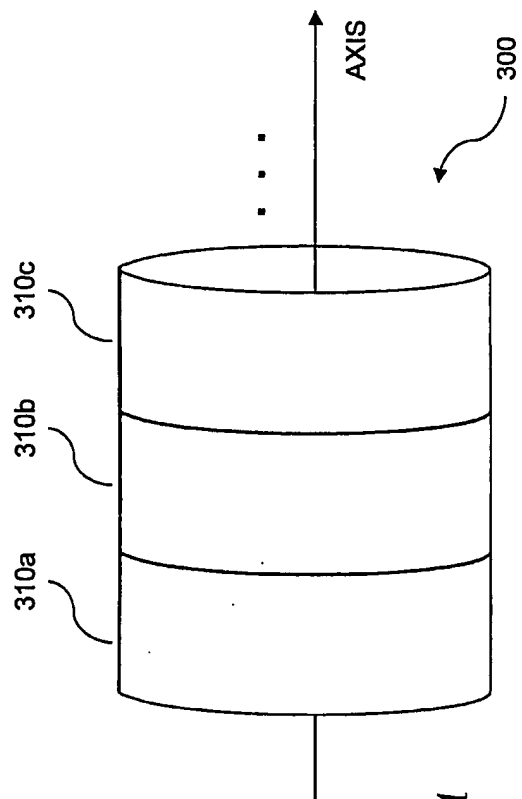


FIGURE 4A

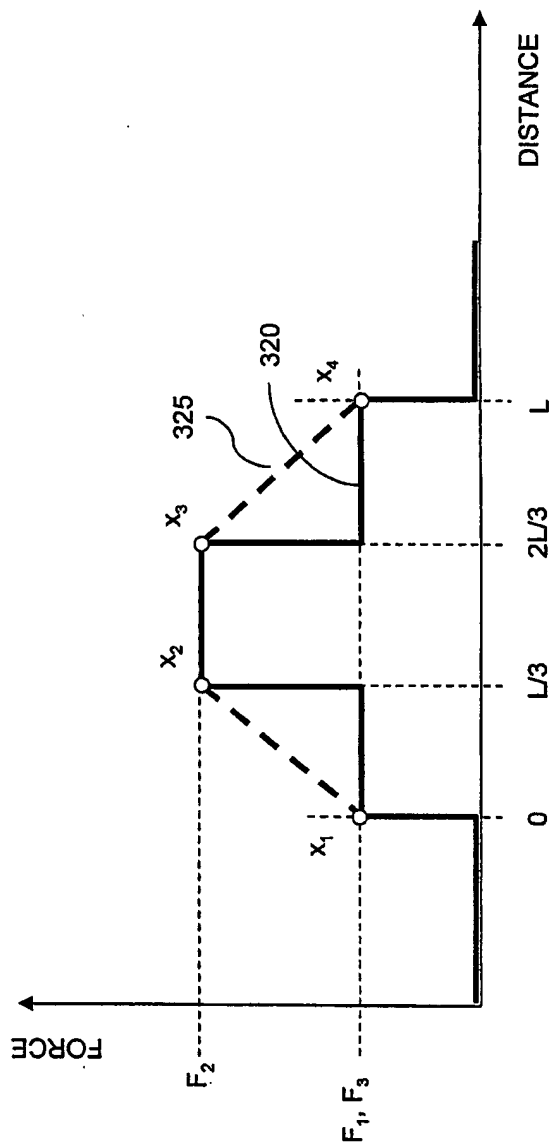


FIGURE 4B

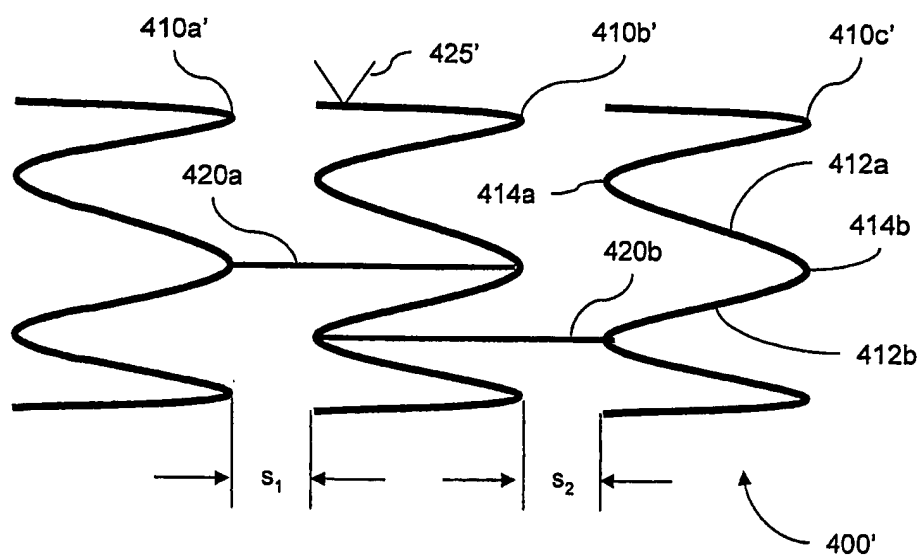


FIGURE 5A

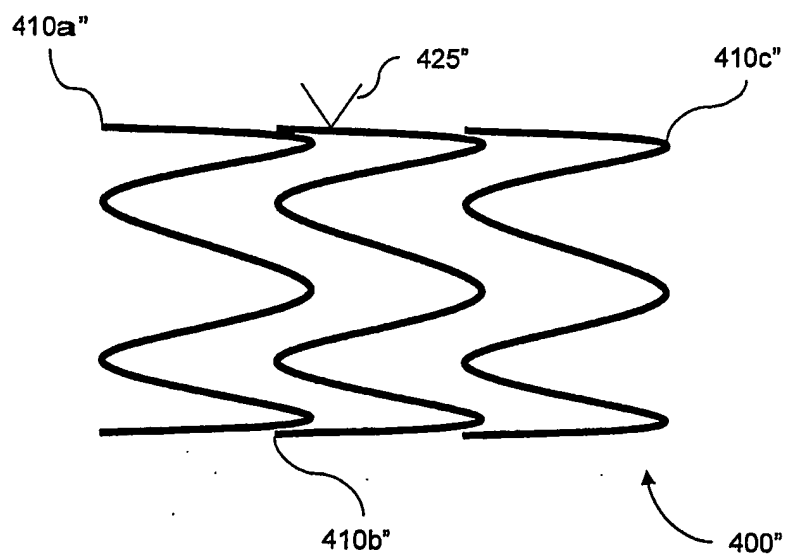


FIGURE 5B

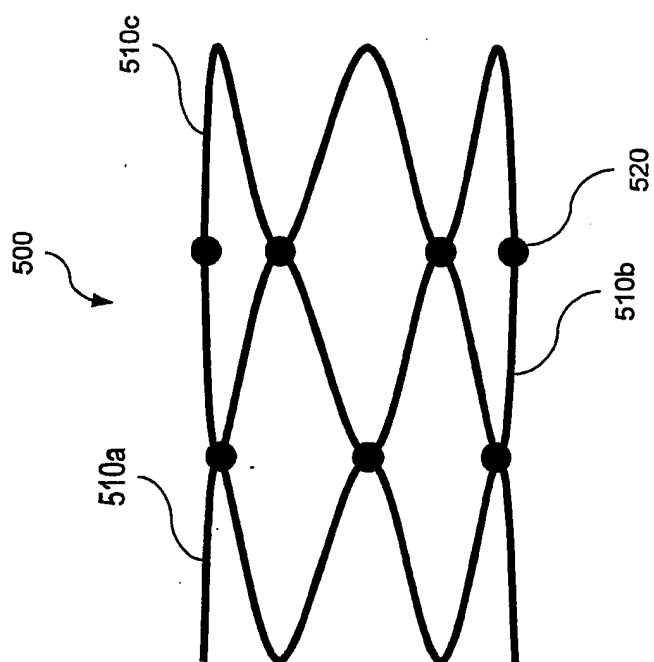


FIGURE 6

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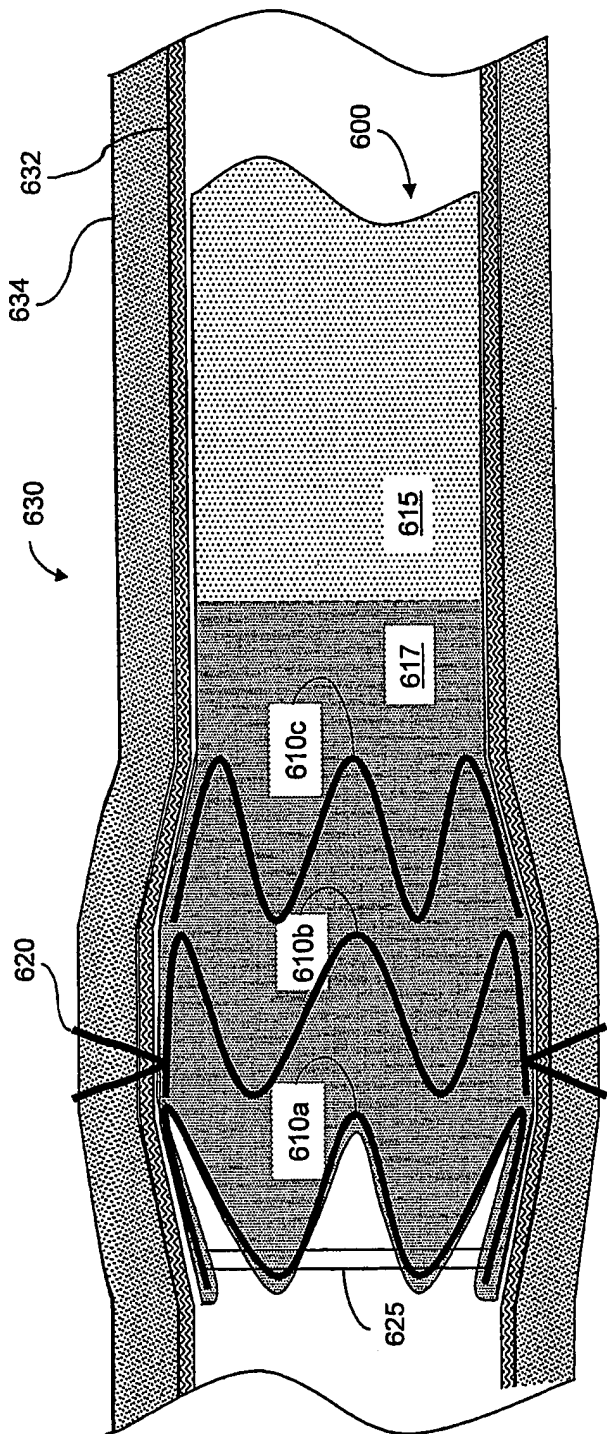


FIGURE 7

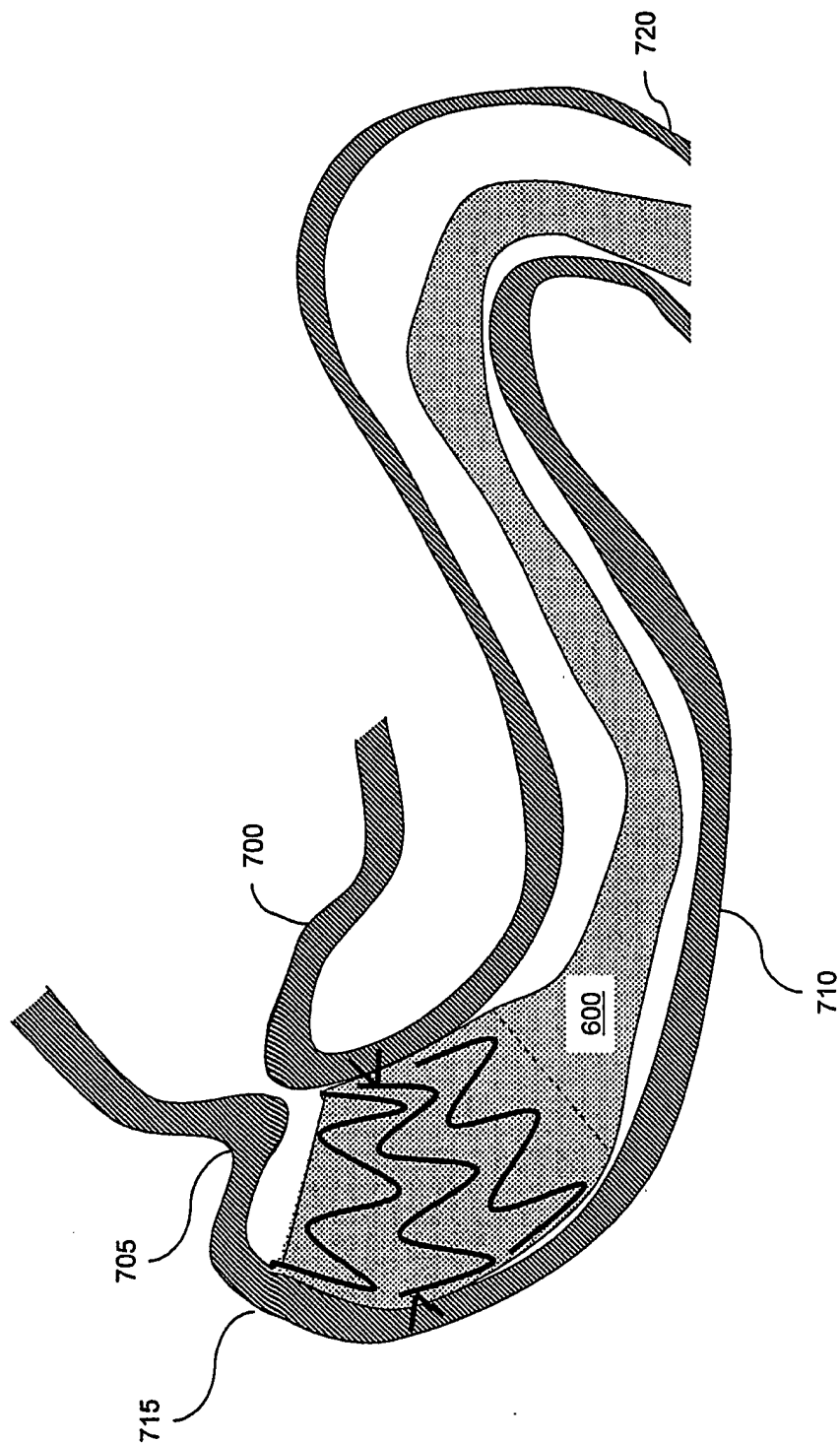


FIGURE 8

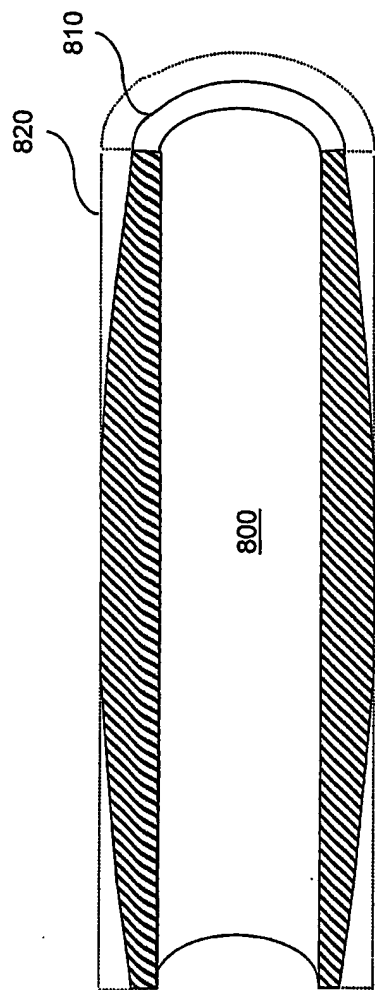


FIGURE 9A

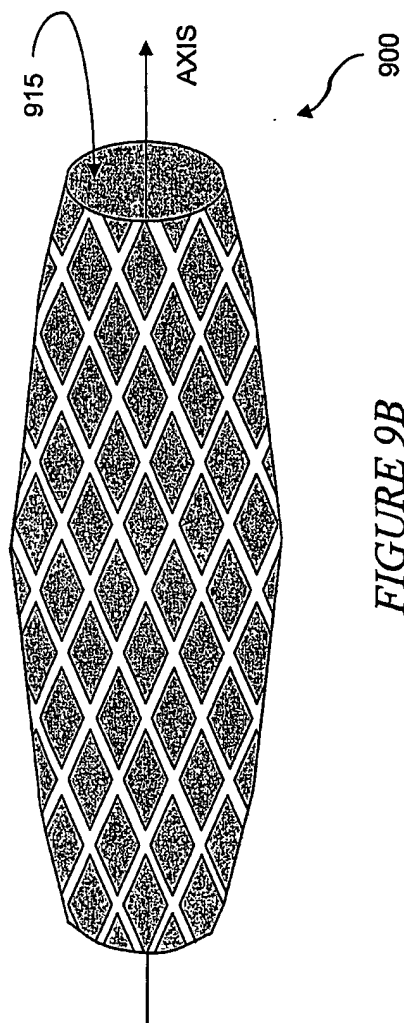


FIGURE 9B

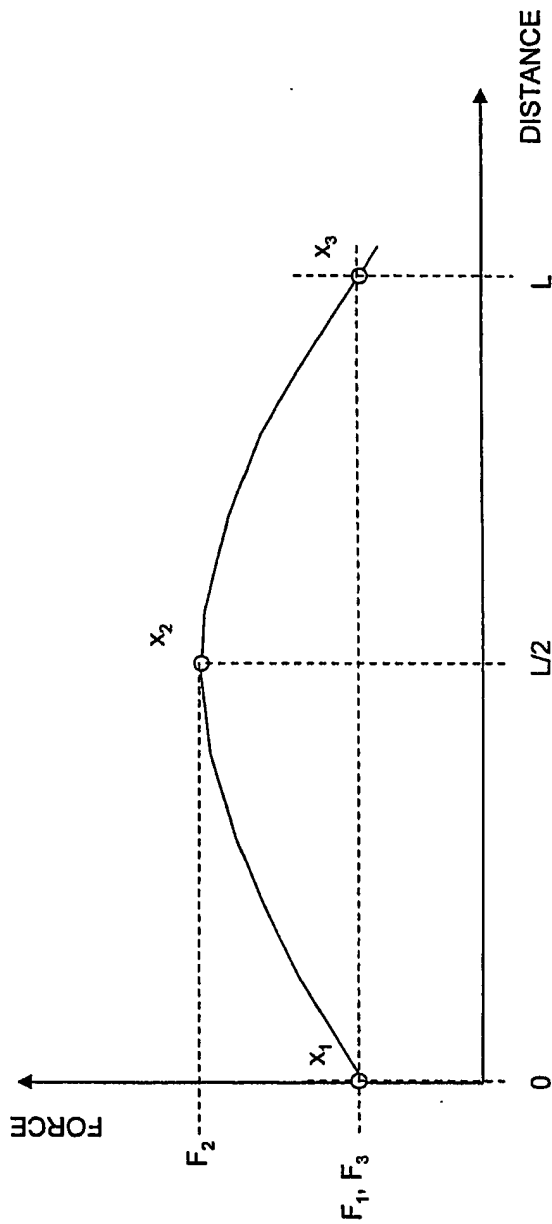


FIGURE 9C

INTERNATIONAL SEARCH REPORT

In Application No
PCT/US2005/033220

A. CLASSIFICATION OF SUBJECT MATTER

A61F2/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/093065 A1 (YACHIA DANIEL ET AL) 13 May 2004 (2004-05-13) page 37 - page 38; figures 5b,6	1,2, 9-13,22, 29
Y	WO 00/42945 A (AL-SAADON, KHALID) 27 July 2000 (2000-07-27) page 9 - page 19; claims; figures	3-8, 14-21
Y	US 2002/177890 A1 (LENKER JAY A) 28 November 2002 (2002-11-28) paragraph '0056! - paragraph '0059!; claims; figure 9a paragraph '0080!	3-8, 14-21
A	WO 00/28922 A (ADVANCED CARDIOVASCULAR SYSTEMS, INC) 25 May 2000 (2000-05-25) the whole document	1-22,29
----- -/-		



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents:

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E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

Z document member of the same patent family

Date of the actual completion of the international search

27 January 2006

Date of mailing of the international search report

03/02/2006

Name and mailing address of the ISA

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Serra i Verdaguer, J

INTERNATIONAL SEARCH REPORT

In Application No
PC17US2005/033220

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2002/065545 A1 (LEONHARDT HOWARD J ET AL) 30 May 2002 (2002-05-30) the whole document -----	1-22, 29

INTERNATIONAL SEARCH REPORT

onal application No.
CT/US2005/033220

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 23-28
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter Application No
PCT/US2005/033220

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2004093065 A1	13-05-2004	AU 2003282343 A1 CA 2505417 A1 EP 1562516 A1 WO 2004043296 A1	03-06-2004 27-05-2004 17-08-2005 27-05-2004
WO 0042945 A	27-07-2000	AU 4596999 A CA 2358453 A1 EP 1148844 A1	07-08-2000 27-07-2000 31-10-2001
US 2002177890 A1	28-11-2002	NONE	
WO 0028922 A	25-05-2000	AU 1472800 A CA 2312566 A1 CN 1287478 A EP 1047357 A1 JP 3626097 B2 JP 2002529193 T	05-06-2000 25-05-2000 14-03-2001 02-11-2000 02-03-2005 10-09-2002
US 2002065545 A1	30-05-2002	NONE	